Medtronic

URGENT FIELD SAFETY NOTICE

FGS-0635 (Bravo™ CF capsule delivery device, 5-pk)

Recall

August 2026

Medtronic Reference: FA1581

EU Manufacturer Single Registration Number (SRN): US-MF-000019982>

Dear Healthcare Professional/ Risk Manager,

The purpose of this letter is to advise you that Medtronic is recalling specific lots of the Bravo CF capsule delivery device, product codes FGS-0635. This recall applies to product with expiration dates prior to and including October 20, 2027 (lot numbers from 64553F up to and including 68912F).

Please note that a subset of these lots was previously included in a recall notification sent to customers and distributors in June 2025. While the issue experienced by customers is the same as that described in the prior recall notification, the underlying cause is different, and this is a separate recall.

Product Scope:

Product Number	**Product Names**	**GTIN**	**Lot Numbers/Expiration Date**
FGS-0635	Bravo CF capsule delivery device, 5-pk	10613994000009	Expiration dates prior to and including October 20, 2027 (lot numbers from 64553F up to and including 68912F)

The Example Product Label below shows the location of the lot number and expiration date (in red boxes) on the Bravo CF capsule delivery devices.

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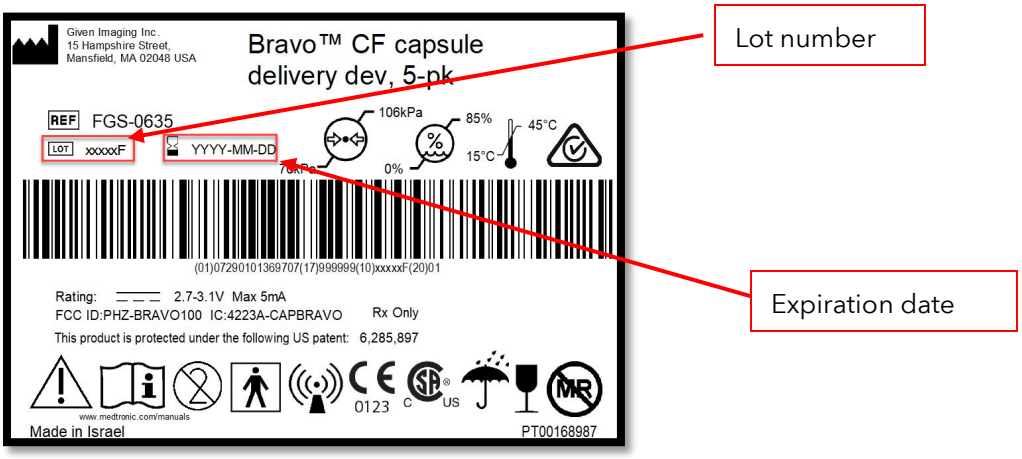

Example Product Label

Issue Description:

Medtronic has identified an increase in complaints involving the Bravo CF capsule delivery device where the capsule fails to attach to the esophagus or detach from the delivery device. Medtronic's preliminary root cause investigation has identified a potential condition impacting the component that controls the deployment of the capsule, which can then be exacerbated by a failure to keep the delivery device straight as instructed in the User Guide, as a potential cause. Risks associated with this issue include patient aspiration/inhalation, perforation of esophagus, obstruction of the airway, hemorrhage/blood loss/bleeding, laceration of the esophagus, a delay in diagnosis, and foreign bodies remaining in the patient.

From January 1, 2025 – July 7, 2026, Medtronic has received 761 complaints for failure to attach or failure to detach, of which 184 included a patient outcome of serious injury. No deaths have been reported.

Medtronic has implemented corrective actions and lots with an expiration date of December 10, 2027, or later are not in scope of this recall and do not need to be returned.

Customer Actions:

- Immediately identify and quarantine all unused and affected devices described above in the product scope.
- Return all unused, affected product(s) to Medtronic.
- Please complete and return the enclosed Customer Acknowledgement Form even if you do not have unused inventory.
- Pass on this notice to all those who need to be aware within your organization or to any organization where the affected product has been transferred or distributed.
- Please maintain a copy of this communication in your records.

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Additional Information:

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic representative.

Sincerely,

Luminita Lungu on behalf of Cristian Rusu

Country Manager

Enclosed:

- Customer Acknowledgement Form
- Appendix A: Affected Lot Numbers of FGS-0635

Appendix A

FGS-0635 (Bravo CF capsule delivery device, 5-pk) Lot Numbers

68259F